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THE USE OF ECONOMIC EVALUATION IN A MEDICAL DEVICE COMMISION OF AN ITALIAN TEACHING HOSPITAL

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OBJECTIVES: In order to control Medical Devices (MDs) purchasing process and to rationalize the MDs evaluation process, the Verona Hospitals (2 accounting for 1.700 beds), have set up a Medical Devices Committee (MDC). MDC members, who have expertise in a broad range of disciplines, evaluate MDs according to Health Technology Assessment (HTA) criteria. This study is concerned with the use of economic evaluations in policy decision making of MDC. **METHODS:** We developed a Data-Base to record all economic evidences considered by MDC from January 2009 to April 2010 for each MD evaluated: health economics analysis in literature (cost-effectiveness, cost-to-cost etc), cost information (price, costs impact etc) and Disease Related Group (DRG) simulation. We verified also the presence and costs of current alternative treatments. **RESULTS:** Among 37 MDs evaluated 30 technologies had at least a current alternative treatment in Hospital formulary (81.1%); MDC always considered at least the price of MDs, costs impact of introducing a new MD and costs when compared with alternative/current treatments (100%). For 23 MDs the management office individuated the DRG value (62.2%) and for 12 of them (32.4%) verified whether DRG covered direct costs. Only for 4 MDs (10.8%) was possible finding at least an economic study in literature (2 cost-effectiveness analysis and 2 cost-to-cost analysis). **CONCLUSIONS:** At the moment the decisions taken by the MDC mainly focused on the clinical benefits, on the comparison of costs vs. alternative treatments and on the incidence of the DM cost on the DRG tariff. The economic evidences seldom influence the opinion of MDC, most of all because the clinical value of DM is not always supported by economic evidences. Recently, technology application form has been modified including questions about the potential savings derived by the new technology, economic studies (also not published) and Budget Impact analysis.

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VALUE OF MULTI-CRITERIA DECISION ANALYSIS IN EARLY ASSESSMENT OF MEDICAL DIAGNOSTIC DEVICES

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OBJECTIVES: Multicriteria decision analytic (MCDA) techniques are a powerful tool in evaluating health care interventions where multiple, often competing, factors need to be considered. The analytic hierarchy process (AHP) is one such technique. We have applied AHP to evaluate medical diagnostic technologies as to support product development and market access. The main objective of this study is to show feasibility of AHP in terms of applicability and outcome. We therefore have studied the expected performance of the Photoacoustic Mammoscope (PAM), a new imaging device for detection of breast cancer based on photoacoustic imaging. **METHODS:** Before starting the study we defined different diagnostic and screening scenarios for the PAM including criteria that are important in the acceptance of the device. We finally defined four strategies including mammography, ultrasound and MRI imaging. The Analytic Hierarchy Process (AHP) analysis was then used to identify the relative importance of evaluation criteria, and to identify the relative performance of four different breast cancer imaging techniques. **RESULTS:** According to the expert panel the most important criterion in the design of a diagnostic breast imaging device is sensitivity (overall weight was 54%). Factors that mainly determine the performance on sensitivity are the visualization of mass margins, mass shape and vascularization. Second most important criterion was safety. **CONCLUSIONS:** From an early assessment of photoacoustic imaging it may be concluded that the potential clinical performance justifies further development and implementation of PAM. However, further research on the use of AHP in medical product development is required. We present and discuss some ideas to further integrate clinical evidence into MCDA using Bayesian techniques as well as sensitivity analyses on the model inputs.

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PERSONALIZED PHARMACOTHERAPY AND ANALYSIS OF EXTEMPORANEOUS DOSAGE FORMS FOR CHILDREN IN UKRAINE

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OBJECTIVES: Pharmacotherapy of children requires the use of drugs for individual preparation of personalized treatment. Medications extemporal manufacturing approach allows for Personalized Medicine. The use of extemporaneous preparations to precisely match the appropriate concentration of drug forms, volume and available dosage forms for komplayensu, extemporaneous medicines do not contain stabilizers, preservatives, it is important for children with allergic diseases. **METHODS:** The ABC—analysis was conducted of 3525 prescription extemporaneous preparations which were made in 8 pharmacies specialized of Western Ukraine regions for 2007–2009. **RESULTS:** The total list of pediatric formulations consisted of 106 items. Determined that the practical range of medicines includes 7 extemporaneous dosage forms, including solutions of 45% solutions, ointments 23% and 12% suspensions et al. Revealed that the production of extemporaneous preparations seasonal influences. Increasing production of liquids, powders at the time of respiratory exacerbation in children. Distinguished set of extemporaneous preparations, which are often assigned practical pediatrician in Ukraine: protargol drops—when rhinitis, cough mixture, powder eufilinu with glucose—with bronchitis, Foenuculi water—with flatulence, pepsin solution with hydrochloric acid—in violation of appetite, anestezynum suspension; dexamethasone ointment, betamethasone ointment—for allergies vitamin powder. Determined extemporaneous medicines for children, which have no analogues in industrial production—a solution of pepsin with hydrochloric acid, dexamethasone ointment, paste Lassara with oil Plum; diazolinum powder with calcium gluconate and glucose—from allergies, suppositories with cocoa butter and levomitsetinum—with diarrhea, Foenuculi water—with flatulence in newborns and infants. **CONCLUSIONS:** Using drugs extemporal medicines, namely those that have no industrial counterparts, to ensure individualized pharmacotherapy children pick up the dose, volume of product, and prevent undesirable side reactions, especially for treatment of chronic diseases in children with allergic manifestations and provide a personalized therapy in pediatric practice.

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IMPACT OF BLEEDING-RELATED CONSEQUENCES ON LENGTH OF STAY (LOS) AND HOSPITAL COSTS IN PATIENTS UNDERGOING SURGERY IN FRANCE

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OBJECTIVES: The objectives of this study were to estimate the incidence, costs and length of stay (LOS) of bleeding-related consequences in various surgical procedures in France. **METHODS:** A retrospective analysis was conducted using the national Diagnosis Related Group (DRG) database (PMSI). Patients with surgical procedures in 2008 were identified based on DRGs. For each DRG, the rate of bleeding-related consequences was estimated. For DRGs with an incidence of bleeding-related consequences over 10%, age and gender-adjusted hospital LOS and costs were examined among patients with (WB) and without bleeding related consequences (WoB). The rates of hospitalizations exceeding the expected LOS (derived from PMSI) between WB and WoB surgeries were compared using multivariate logistic regression. **RESULTS:** Of the 88 different DRGs in French database, 24 (a total of 321,657 hospitalizations) had an incidence of bleeding-related consequences over 10%, ranging from 10.3% to 25.3%. DRGs with higher rates were transplantations, cardiac and major orthopedic surgery, vascular and solid organ surgery. Age and gender adjusted mean LOS for WB patients was 3.38 days longer (+26.5%) compared with WoB patients ($P < 0.001$). Average adjusted costs were estimated at €12,087 per WB stays versus €10,086 per WoB stays, corresponding to a 19.9% increase ($P < 0.001$). The rate of hospitalizations exceeding the expected LOS was respectively 42.3 % and 37.0% for WB and WoB hospitalizations ($P < 0.001$). WB hospitalizations were approximately 10% more likely to exceed expected LOS compared to WoB (OR = 1.09, 95% CI: 1.07–1.11, $P < 0.001$), after adjusting for patient characteristics. **CONCLUSIONS:** This study characterizes the increased hospital LOS and cost among patients with bleeding-related consequences in France. In particular, the excess LOS than expected DRG LOS presents significant financial burden related to bleeding consequences for hospitals. Awareness of potential clinical and economic impacts of bleeding-related consequences provides important framework for understanding the value of blood-conservation strategies.

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THE EXAMINATION OF THE CHRONIC STRESS

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OBJECTIVES: We examined the effects of chronic stress with modelling different shift work schedules in animal experimental model. **METHODS:** Internationally most frequently used night shift schedules were applied in three groups of animals (4DL/3LD; 8DL/6LD; 2DL/2LD) beside a group kept in normal LD cycle (12 hour light-L/12 hour dark-D = control group). Groups were divided in two parts, one of them were exposed to CMS. Degree of anxiety was evaluated in light-dark box. Differences between groups according to variables (sex, lighting regimens and CMS) and time spent in light, number of changing compartments and latency of changing dark to the light section were examined with multiple one-way analysis of variance. Plasma concentrations of corticosterone and testosterone were measured after 4 weeks of exposure to stress procedures, concentrations were determined by radioimmunoassay. **RESULTS:** In groups kept under different lighting schedules compared to control group, significant differences were found: animals kept in 4DL/3LD ($p = 0.05$, $p = 0.079$ /nearly significant/ $p = 0.011$) and 2DL/2LD ($p = 0.025$, $p = 0.001$, $p = 0.045$) schedules spent less time in light, latency increased, while no statistically significant differences were found in 8DL/6LD group in any of the variables ($p = 0.113$, $p = 0.118$, $p = 0.45$). We found that groups kept in different lighting schedules and exposed to chronic stress kept their circadian rhythm (corticosterone: $p = 0,095$—border line statistical significance; testosterone: $p = 0.004$), while groups kept in different lighting schedules but not exposed to chronic stress lost circadian rhythms (corticosterone: $p = 0.071$ for 12-hour component; testosterone: $p > 0.20$). **CONCLUSIONS:** According to light-dark box test and hormonal examinations it seems, that shifts different than normal light/dark regimen lead to anxiety also without CMS, and may have been harder load than the CMS procedure. Group 8DL/6LD shows the closest approximations of parameters observed in LD group suggesting that this schedule applied in shift work is less harmful to health, and provides the best way of regeneration.